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Title: INJECTION MOLDING METHOD FOR (METH)ACRYLATE COPOLYMERS CONTAINING NEUTRAL AND ACIDIC GROUPS.

Abstract: The invention relates to a method for producing molded bodies by injection that comprises the following steps: A) melting a mixture from a) a (meth)acrylate copolymer that is composed of 40 to 100% by weight of radically polymerized C_1 to C_4 alkyl esters of acrylic or methacrylic acid and 0 to 60% by weight of (meth)acrylate monomers with an anionic group in the alkyl radical. Said (meth)acrylate copolymer contains b) 0.1 to 3% by weight of a parting compound. Optionally, c) 0 to 50% by weight of a desiccant, d) 0 to 30% by weight of a softener, e) 0 to 100% by weight of additives or adjuvants, f) 0 to 100% by weight of a pharmaceutical agent, and g) 0 to 20% by weight of another polymer or copolymer can be contained in the mixture. The quantities indicated of components b) to g) relate to the (meth)acrylate copolymer a) and the mixture has a content of more than 0.5% by weight of low-boiling components with a vapor pressure of at least 1.9 bar at 120°C before the mixture is melted. The inventive method further comprises the steps B) degassing the mixture in the thermoplastic state at temperatures of at least 120°C, thereby reducing the content of low-boiling components with a vapor pressure of at least 1.9 bar at 120°C to no more than 0.5% by weight, and C) injecting the molten and degassed mixture into the mold cavity of an injection-molding tool, said mold cavity having a temperature that is at least 10°C below the glass transition temperature of the (meth)acrylate copolymer. The molten mixture is then cooled and the resulting molded body is removed from the mold.

Injection-molding method for (meth)acrylate copolymers containing neutral and acidic groups

The invention relates to a procedure for producing molded bodies by injection molding, the molded bodies themselves and their use for pharmaceutical purposes.

Prior Art

US 5,644,001 concerns a coating and binding agent that is soluble in intestinal juice for medicinal forms containing copolymers from 10 to 25% by weight methacrylic acid, 40 to 60% by weight methacrylate and 20 to 40% by weight methylmethacrylate. It is applied as an aqueous dispersion or an organic solution.

EP 0,704,207 A2 describes thermoplastic synthetics for medicine containers that are soluble in intestinal juice. This involves mixed polymers from 16 to 40% by weight acrylic or methacrylic acid, 30 to 80% by weight methacrylate and 0 to 40% by weight other alkyl esters of acrylic acid and/or methacrylic acid.

In the example, corresponding mixed polymers are melted at 160°C and are mixed after the addition of 6% by weight glycerine monostearate. The mixture is broken and ground to a powder. The powder is loaded into the feed chamber of an injection transfer mold and injected under a pressure of 150 bar through an opening 0.5 mm wide into the mold cavity. After cooling, bubble-free, slightly opaque, thin-walled capsules for medicine are obtained. Special steps for removing low-boiling components immediately before injection mold processing are not disclosed.

Task and Solution

The task was seen to be to provide a procedure that is further developed compared with EP 0,704,207 A2 which allows neutral or anionic (meth)acrylate copolymers to be processed in the injection molding process in such a way that injection molding die impurities are kept to a minimum and high yields of molded bodies with no cracks or streaks are obtained with only slight waste. Molded bodies had to be obtained that met high mechanical requirements, were dimensionally exact so as to be easily connected with other molded bodies and possess a smooth, closed surface with no pores or furrows and are therefore suitable as carriers or containers for pharmaceutically active substances, such as, for example, capsules (two-piece capsules) or parts.

The task is solved by a method for producing molded bodies by means of injection molding

with the following steps:

A) Melting a mixture made up of

a) a (meth)acrylate copolymer which comprises 40 to 100% by weight of radically polymerized C_1 to C_4 alkyl esters of acrylic or methacrylic acid

and 0 to 60% by weight (meth)acrylate monomers with an anionic group in the alkyl radical, which contains 0.1 to 3% by weight of a parting agent

and optionally

c) 0 to 50% by weight of a desiccant

d) 0 to 30% by weight of a softener

e) 0 to 100% by weight of additives or adjuvants

f) 0 to 100% by weight of a pharmaceutical substance

g) 0 to 20% by weight of another polymer or copolymer

may be contained in the mixture, the indicated quantities of components b) through g) relating to the (meth)acrylate copolymer and

the mixture having, before melting, a content of more than 0.5% by weight of low-boiling components with a vapor pressure of at least 1.9 bar at 120°C.

B) Degassing the mixture in the thermoplastic state at temperatures of at least 120°C, whereby the content of low-boiling components with a vapor pressure of at least 1.9 bar at 120°C is lowered to no more than 0.5% by weight.

C) Injecting the molten and degassed mixture into the mold cavity of an injection molding die, the mold cavity having a temperature that is at least 10°C below the glass transition temperature of the (meth)acrylate copolymer; cooling the molten mixture and removing the resulting molded body from the mold.

New injection-molded bodies can be obtained with the invention that meet high mechanical requirements, are dimensionally exact so as to be easily connected with other molded bodies, possess a smooth, closed surface with no pores or furrows and have high temperature stability.

Embodiment of Invention

The method of the invention for producing molded bodies by means of injection molding is divided into steps A), B) and C).

A) Melting a mixture made up of

a) a (meth)acrylate copolymer which comprises 40 to 100% by weight of radically polymerized C_1 to C_4 alkyl esters of acrylic or methacrylic acid and 0 to 60% by weight (meth)acrylate monomers with an anionic group in the alkyl radical, which

b) contains 0.1 to 3% by weight of a parting agent

and optionally

c) 0 to 50% by weight of a desiccant

d) 0 to 30% by weight of a softener

e) 0 to 100% by weight of additives or adjuvants

f) 0 to 100% by weight of a pharmaceutical substance

g) 0 to 20% by weight of another polymer or copolymer

may be contained in the mixture, the indicated quantities of components b) through g) relating to the (meth)acrylate copolymer and

the mixture having, before melting, a content of more than 0.5% by weight of low-boiling components with a vapor pressure of at least 1.9 bar at 120°C.

The copolymer, which is present in granulate or powder form, is melted preferably in an extruder at a temperature of 120°C to 250°C.

The Mixture

The mixture consists of components a) and b), and optionally c) through g).

The (Meth)acrylate Copolymer a)

The (meth)acrylate copolymer consists of 40 to 100, preferably 45 to 99, and especially 85 to 95% by weight of radically polymerized C_1 through C_4 alkyl esters of acrylic or methacrylic acid and may contain 0 to 60, preferably 1 to 55, and especially 5 to 15% by weight of (meth)acrylate monomer with an anionic group in the alkyl radical.

C_1 to C_4 alkyl esters of acrylic or methacrylic acid are, in particular, methylmethacrylate, ethylmethacrylate, butylmethacrylate, methylacrylate, ethylacrylate and butylacrylate.

A (meth)acrylate monomer with an anionic group in the alkyl radical may be, for example, acrylic acid but preferably methacrylic acid.

Neutral (meth)acrylate copolymers from 20 to 40% by weight ethylacrylate and 60 to 80% by weight methylmethacrylate (EUDRAGIT® NE type) are suitable, for example.

Also suitable are anionic (meth)acrylate copolymers from 40 to 60% by weight methacrylic acid and 60 to 40% by weight methylmethacrylate or 60 to 40% by weight ethylacrylate (EUDRAGIT® L or EUDRAGIT® L100-55 types).

Also suitable are anionic (meth)acrylate copolymers from 20 to 40% by weight methacrylic acid and 80 to 60% by weight methylmethacrylate (EUDRAGIT® S type).

Particularly well suited are (meth)acrylate copolymers from 10 to 30% by weight methylmethacrylate, 50 to 70% by weight methylacrylate and 5 to 15% by weight methacrylic acid (EUDRAGIT® FS type).

The copolymers are obtained in the familiar manner by radical substance, solution, pearl or emulsion polymerization. Before processing, they must be made to match the particle size range of the invention by grinding, drying or spraying processes. This can be done by simple breaking of extruded and cooled granulate strands or hot sprueing.

The use of powders may be beneficial, especially when mixing with other powders or liquids. Suitable equipment for producing the powder is familiar to the specialist, for example, air jet mills, pinned disk mills, fan mills. Optionally, corresponding screening steps can be used. A suitable mill for large industrial quantities is, for example, a counter jet mill (Multi No. 4200), which operates at approx. 6 bar.

Parting Agent (Mold Release Agent b)

The mixture contains 0.1 to 3, preferably 0.2 to 1% by weight of a parting agent relative to the (meth)acrylate copolymer.

Unlike desiccants, parting agents have the property of reducing the adhesive strength between the molded parts and the wall of the die in which the molded part is produced. This makes it possible to produce molded parts which do not break and are not geometrically deformed when removed from the mold. Parting agents are usually somewhat or completely incompatible with the polymers in which they are particularly effective. Due to the partial or total incompatibility when the molten mass is injected into the mold cavity, there is a migration into the transition interface between die wall and molded part.

For parting agents to be able to migrate particularly effectively, the melting point of the parting agent must be 20°C to 100°C below the processing temperature of the polymer.

Examples of parting agents (mold release agents) are: esters of fatty acids or fatty acid amides, aliphatic, long-chained carboxylic acids, fatty alcohols and their esters, montan or paraffin wax and metal soaps, with special mention for glycerol monostearate, stearyl alcohol, glycerol behenic acid ester, cetyl alcohol, palmitic acid, carnauba wax, beeswax, etc.

Desiccant c)

The mixture may contain 0 to 50, preferably 10 to 30% by weight of a desiccant relative to the (meth)acrylate copolymer.

Desiccants have the following properties: they affect large specific surfaces, are chemically inert, are readily pourable and finely divided. Due to these properties, they can be effectively homogeneously distributed in molten masses and lower the adhesiveness of polymers which contain highly polar comonomers as functional groups.

Examples of disiccants are:

Aluminum oxide, magnesium oxide, kaolin, talcum, silicic acid (aerosils), barium sulfate, soot and cellulose.

Softener d)

The mixture may contain 0 to 30, preferably 0.5 to 15% by weight of a softener relative to the (meth)acrylate copolymer.

The addition of softeners causes the molded body to be less brittle. This reduces the number of broken molded bodies after removal from the mold. Without softeners, the percentage of perfect molded bodies removed from the mold in most mixtures is usually approximately 85%. With softeners added, the mold removal breakage percentage can be reduced so that yields can usually be increased to 95 to 100%.

Substances suitable as softeners usually have a molecular weight of between 100 and 20,000 and contain one or more hydrophilic groups in the molecule, e.g., hydroxyl, ester or amino groups. Citrates, phthalates, sebacates and castor oil are suitable. Examples of suitable softeners are citric acid alkylester, glycerine ester, phthalic acid alkylester, sebacic acid alkylester, sucrose ester, sorbitane ester, dibutyl sebacate and polyethylene glycols 400 g/mol to 20,000 g/ml.

Preferred softeners are tributyl citrate, triethyl citrate, acetyltriethyl citrate, dibutyl sebacate and diethyl sebacate.

Additives or Adjuvants e)

The mixture may contain 0 to 100% by weight of pharmaceutically standard additives or adjuvants relative to the (meth)acrylate copolymer.

These include, for example, stabilizers, dyes, antioxidants, wetting agents, pigments, brighteners, etc.

Pharmaceutically Active Substance f)

The mixture may contain 0 to 100% by weight of one or more pharmaceutically active substances relative to the (meth)acrylate copolymer.

Such pharmaceutically active substances must be used that do not decompose at processing temperature.

The medicines used in the invention (pharmaceutically active substances) are intended to be applied in the human or animal body to

1. heal, alleviate, prevent or identify diseases, ailments, bodily injury or pathological complaints;

2. to reveal the condition, state or functions of the body or mental states;

3. to replace substances or bodily fluids produced by the human or animal body;

4. to fend off, eliminate or render harmless pathogens, parasites or foreign substances; or

5. to influence the condition, state or functions of the body of mental states.

Currently used medicinal substances can be found in reference books such as, for example, the Red List or the Merck Index.

In the invention, all substances can be used which have the desired therapeutic effect as defined above and possess sufficient stability and the ability to penetrate through the skin.

Important examples (groups and individual substances) include but are not limited to the following:

Analgesics,
Antiallergics, antiarrhythmics,
Antibiotics, chemotherapeutics, antidiabetics, antidotes,
Antiepileptics, antihypertensives, antihypotensives,
Anticoagulants, antimycotics, antiphlogistics,
Beta receptor blockers, calcium antagonists and ACE inhibitors,
Broncholytics/antiasthmatics, cholinergics, corticoids (internal),
Dermatics, diuretics, enzyme inhibitors, enzyme preparations and
Transport proteins,
Expectorants, geriatrics, antipodagrics, influenza remedies,
Hormones and their inhibitors, hypnotics/sedatives, cardiacs, lipid lowerers,
Parathyroid hormones/calcium metabolism regulators,
Psychopharmaceuticals, sex hormones and their inhibitors,
Spasmolytics, sympatholytics, sympathomimetics, vitamins,
Wound treatment agents, cytostatics.

Examples of substances suitable for filling molded bodies (capsules) or for incorporation into the molded bodies are: ranitidine, simvastatin, enalapril, fluoxetine, amlodipine, amoxicillin, sertraline, nifedipine, ciprofloxacin, acyclovir, lovastatin, epoetin, paroxetine, captopril, nabumetone, granisetron, cimetidine, ticarcillin, triamterene, hydrochlorothiazide, verapamil, paracetamol, morphine derivatives, topotecan or the pharmaceutically used salts.

Other Polymers or Copolymers g)

The mixture may contain 0 to 20% by weight of another polymer or copolymer relative to the (meth)acrylate copolymer.

To control the release of active substance, it may be beneficial in the individual case to mix in other polymers. The percentage of other polymers in the mixture is, however, not more than 20% by weight, preferably a maximum of 10% by weight, and especially 0 - 5% by weight, relative to the (meth)acrylate copolymer.

Examples of such other polymers are: polyvinyl pyrolidones, polyvinyl alcohols, cationic (meth)acrylate copolymers from methylmethacrylate and/or ethylacrylate and 2-dimethylaminoethylmethyl acrylate (EUDRAGIT® E100), carboxymethyl cellulose salts, hydroxypropyl cellulose (HPMC), neutral (meth)acrylate copolymers from methylmethacrylate and ethylacrylate (dry substance from EUDRAGIT® NE 30D), copolymers from methylmethacrylate and butylmethacrylate (PLASTOID® B) or (meth)acrylate copolymers with quaternary ammonium groups, containing trimethylammoniummethylmethacrylate chloride as a monomer (EUDRAGIT® RL and EUDRAGIT® RS respectively).

Low-Boiling Components

In its commercial form, the familiar (meth)acrylate copolymer almost always has content of more than 0.5% by weight of low-boiling components with a vapor pressure of at least 1.9 bar at 120°C. The standard amounts of these components are in the range of 0.7 to 2.0% by weight. The low-boiling components primarily involve water that is absorbed from the air humidity or is included in the production process of the polymers.

Step B)

Degassing the mixture at temperatures of at least 120°C, preferably at a minimum of 150°C and a maximum of 250°C, whereby the content of low-boiling components with a minimum vapor pressure of 1.9 bar at 120°C is reduced to a maximum of 0.5% by weight, preferably a maximum of 0.2% by weight, and especially a maximum of 0.1% by weight. This prevents any sudden undesired out-gassing during the injection molding process in step c) that would lead to the formation of bubbles or foaming within the molded body being created that would make it unusable.

Since the listed (meth)acrylate copolymers either have a low glass transition temperature and may therefore stick together even at low temperatures or are thermally labile, low-boiling components cannot usually be removed by simple drying at a high temperature.

Degassing step b) is therefore performed preferably by extrusion drying by means of an extruder with a degassing zone or by means of injection molding equipment with an injection molding die with a preceding degassing opening.

For effective degassing operation, a vacuum-producing pump (e.g., a water jet pump) can also be installed at the degassing opening of the extruder or the injection molding machine. The partial vacuum that can be created in this way leads to further removal of the low-boiling components, such as, for example, moisture from the molten masses. Partial vacuums created in this way can be from 800 mbar to 10 mbar.

The degassed extruded material obtained by extrusion drying in an extruder with a degassing zone can be fed directly to the injection molding machine with no further steps to remove low-boiling components and can be processed directly into molded bodies.

In the case of degassing on an injection molding installation with a degassing opening in the injection molding cylinder, degassing is performed before the molten plastic mass is pressed into the injection molded shape by means of said degassing opening in the injection molding cylinder.

Step C)

Injecting the molten and degassed mixture into the mold cavity of an injection molding die, the mold cavity having a temperature that is at least 10°C, preferably at least 12°C, and ideally at least 15°C, especially at least 25°C or even at least 35°C below the glass transition temperature of the (meth)acrylate copolymer, cooling the molten mixture and removing the resulting molded body from the mold.

The thermoplastic processing is performed in the familiar manner by means of an injection molding machine at temperatures in the range of 80 to 220°C, especially between 120°C and 160°C and at pressures of 60 to 400 bar.

The mold temperature is, at glass transition temperatures, lower depending on the (meth)acrylate copolymers used in a range of, for example, 40°C to 80°C, for example at a maximum of 30 or a maximum of 20°C so that the copolymer can be solidified a short time after the injection process in the mold and the finished molded body can be removed from the mold.

The molded bodies can be removed from the mold cavity of the injection molding die without breaking and have an even, compact, blemish-free surface. The molded body is distinguished by a mechanical stability under load or elasticity and resistance to breakage.

It has, in particular, an ISO 179 impact strength measured on test specimens of at least 5 KJ/m^2, preferably at least 10 KJ/m^2, and ideally 15 KJ/m^2.

The VST (A10) thermal stability, measured on test specimens according to ISO 306, is approximately between 30°C and 60°C.

The molded bodies obtained by the invention may have, for example, the form of a capsule, part of a capsule, e.g., a capsule half, or a two-part capsule, serving as a container for a pharmaceutically active substance. Active substance can be inserted, for example in the form of pellets, and the two capsule halves can then be joined together by adhesion, or by laser, ultrasonic or microwave welding, or by means of a snap connection.

According to this method, capsules made of different material (e.g., gelatines, anhydrolyzed starch, HPMC or other methacrylates) can be combined with each other. The molded body may therefore also be part of a dosage unit.

Other forms, such as tablets or lense geometries, are possible. In this case the compound used for the injection molding already contains the pharmaceutical substance. In the final form, the active substance is distributed as evenly as possible in crystalline (solid dispersion) or dissolved (solid solution) form.

EXAMPLES

Example 1: Molded Body Soluble in Intestinal Juice

10 kg of a (meth)acrylate copolymer in granulate form, consisting of methylmethacrylate, methylacrylate and methacrylic acid in a 25:65:10 ratio, are placed in a 30 liter mixing container made of stainless steel, and 12.5 g stearyl alcohol (0.25% by weight) are weighed in. The contents are then mixed for 5 minutes on an asymmetric mixer. The mixture produced were placed on a Leistritz LMS 30.34 twin screw extruder to produce a compound according to the invention.

The set melting temperature was 180°C at a screw speed of 120 rpm.

After a length of 50% of the total length of the twin screw extruder, there is an opening in the cylinder wall via which triethyl citrate in an amount of 1% relative to the polymer amount is pumped in by means of a membrane pump. After a mixing zone for the homogenization of the mixture, there is a degassing opening in the screw cylinder which has a opening to the environment. Vapor can be observed coming out of the degassing zone. Four strands were molded from the extruder by means of a nozzle, drawn off via a cooled plate and cut into granulate. The moist granulate content obtained was found to be 0.08% by the K. Fischer method. Examination of the non-extruded starting granulate revealed a water content of 1.2%.

Injection Molding Processing of the Granulate Obtained

The degassed and granulated mixture thus obtained was put into the funnel of an injection molding machine (Allrounder 250-125, Arburg Co.) and injection molded into capsules.

A quadruple injection molding die with a cold-gate gating system was used. The capsules have a length of 16 mm, a mean outside diameter of 6.8 mm that is reduced to 4 mm toward the closed end, and a wall thickness of 0.6 mm.

The following temperatures were set on the injection molding machine: zone 1 (feed zone): 70°C; zone 2: 160°C; zone 3: 160°C; zone 4: 160°C; zone 5 (nozzle): 130°C. Injection pressure 60 bar, dwell pressure 50 bar, dynamic pressure 3 bar. Die temperature: 17°C

After injection of the molten mass and a dwell pressure time of 6 seconds, the die was opened after a cooling time of 18 seconds and the capsules were removed. The molded parts were able to be removed from the injection molding die with no breakage. Transparent capsules were obtained that are mechanically stable and may be used for further tests.

After the injection molding of 300 injection operations, the cycle was interrupted to verify the mold surface. No coating could be found. The polished mold surface is metallically bright with a high gloss.

Example 2: (Example for Comparison)

A mixture was produced as in the example in EP 0,704,207 A2. Instead of the copolymers described in that patent, a (meth)acrylate copolymer in granulate form, consisting of methylmethacrylate, methylacrylate and methacrylic acid in a 25:65:10 ratio was used and mixed with 6% by weight glycerol monostearate in accordance with EP 0,704,207.

10 kg of the (meth)acrylate copolymer and 600 g glycerol monostearate were continuously added via a gravimetric dosing device into the feed zone of the twin-screw extruder.

The components were homogeneously mixed into the molten mass in the extruder at a screw speed of 120 rpm and a melting temperature of 160°C.

The granulate was placed on the injection molding machine as in Example 1 and processed with the parameter setting being respected.

After 14 injection cycles, dull areas could be found on the surfaces of the capsules produced. The injection cycle was interrupted and the injection molding die was inspected. A coating was found on the highly polished surfaces of the die inserts. The coating was wiped off with cotton wool soaked in acetone and analyzed. Glycerol monostearate was found.

Example 3: (Example for Comparison)

A mixture (compound) was produced on the twin-screw extruder as in Example 1, but the degassing opening at the end of extruder was closed.

The moisture content of the granulate obtained was found to be 1.2% water using the K. Fischer method.

The granulate obtained was applied to the injection molding machine and processed as described in Example 1. The capsules obtained showed surface defects such as streaks, furrows and uneveness and do not meet the requirements set.

CLAIMS

1. Method for producing molded bodies by means of injection molding

with the steps

A) Melting a mixture made up of

a) a (meth)acrylate copolymer which comprises 40 to 100% by weight of radically polymerized C_1 to C_4 alkyl esters of acrylic or methacrylic acid and 0 to 60% by weight (meth)acrylate monomers with an anionic group in the alkyl radical, which contains 0.1 to 3% by weight of a parting agent

and optionally

c) 0 to 50% by weight of a desiccant

d) 0 to 30% by weight of a softener

e) 0 to 100% by weight of additives or adjuvants

f) 0 to 100% by weight of a pharmaceutically active substance

g) 0 to 20% by weight of another polymer or copolymer

may be contained in the mixture, the indicated quantities of components b) through g) relating to the (meth)acrylate copolymer and

the mixture having, before melting, a content of more than 0.5% by weight of low-boiling components with a vapor pressure of at least 1.9 bar at 120°C.

B) Degassing the mixture in the thermoplastic state at temperatures of at least 120°C, whereby the content of low-boiling components with a vapor pressure of at least 1.9 bar at 120°C is lowered to no more than 0.5% by weight.

C) Injecting the molten and degassed mixture into the mold cavity of an injection molding die, the mold cavity having a temperature that is at least 10°C below the glass transition temperature of the (meth)acrylate copolymer; cooling the molten mixture and removing the resulting molded body from the mold.

2. Method as in Claim 1, characterized in that the degassing step b) is performed by means of an extruder with a degassing zone or by means of an injection molding installation with a degassing opening preceding the injection molding die in the injection molding cylinder.

3. Method as in Claim 1 or 2, characterized in that the (meth)acrylate copolymer contains 1 to 50% by weight methacrylic acid as a (meth)acrylate monomer with an anionic group in the alkyl radical.

4. Method as in one or more of Claims 1 through 3, characterized in that the mixture contains 0.5 to 25% by weight of a softener.

5. Injection molded body that can be produced in accordance with one or more of Claims 1 through 4.

6. Molded body as in Claim 5, characterized in that it has an impact strength according to ISO 179 of at least 5 KJ/m^2.

7. Molded body as in Claim 5 or 6, characterized in that it involves a capsule, part of a capsule or part of a dosage unit.

8. Molded body as in Claim 5 or 6, characterized in that it contains a pharmaceutically active substance.

9. Use of a molded body in accordance with one or more of Claims 5 through 8 as a container or carrier for a pharmaceutically active substance.